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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce House of Representatives

April 1986

VETERANS ADMINISTRATION

Drug Company-Sponsored Research at VA Medical Facilities

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Human Resources Division
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April 24, 1986

The Honorable John D. Dingell
Chairman, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report is submitted in response to your October 3, 1984, request for information on drug companies' medical research activities in Veterans Administration (VA) facilities. Based on your request and later agreements with your office, our review included:

1. Examining VA's research involvement with drug companies, including (a) the extent of such research and benefits to VA, (b) the purposes for which drug companies sponsor the research and conditions for use of their funds, and (c) VA's nonfinancial controls over drug company-sponsored research.

2. Determining whether VA's practice of using drug company donations for medical research violates federal prohibitions against an agency supplementing its appropriations.

3. Reviewing VA's procedures concerning financial controls imposed on investigators conducting such research.

4. Determining whether VA recovers all costs of performing drug company-sponsored studies.

5. Reviewing VA investigations of allegations involving drug company-funded research at the Long Beach VA Medical Center that (a) Dr. Wilbert S. Aronow, a former cardiologist at the center, did not obtain informed consent from his research subjects; (b) eight of his coauthors on research publications accepted unauthorized remuneration from drug companies; and (c) five other medical investigators received unauthorized remuneration and conducted research without proper VA authorization.

Our findings and recommendations are summarized in this letter and detailed in appendix I.

Findings

VA Research Involvement With Drug Companies

During fiscal year 1984, the latest period for which VA data were available at the time of our review, drug companies provided at least $26.6 million to support at least 715 medical research studies at about 81 VA medical centers. Of the total, about $9.4 million was donated to VA's General Post Fund[1] and about $17.2 million was provided to outside institutions (i.e., VA-affiliated medical schools or university foundations). For 44 of the 81 VA centers that reported conducting drug company-sponsored research in fiscal year 1984, VA data on the number of studies and funding amounts were incomplete or not readily available; therefore, the amounts cited above are understated.

VA believes that drug company support of research meets the agency's primary mission—patient care—and helps VA satisfy its statutory mandate to conduct a medical research program. Research sponsored by drug companies can, according to VA officials, provide veterans early access to new drug treatments and allow VA investigators to obtain discretionary funds for research and become familiar with new treatment methods. We found these determinations by VA to be reasonable.

Drug companies finance VA research to test their drugs on VA patients in clinical settings, according to company officials with whom we met. Usually, the companies provide VA with research protocols (descriptions of research objectives and methodologies) that comply with Food and Drug Administration (FDA) testing requirements. FDA regulates the marketing and testing of new drugs in the United States. To ensure that VA investigators comply with the protocols and FDA requirements, the drug companies usually impose certain conditions, such as reviewing all study data.

All proposals for VA research studies, including those sponsored by drug companies, must be evaluated and approved by the research and development committee of the VA medical center at which the research will be conducted, regardless of where the funds are deposited. These committees monitor study progress and must approve any major changes to the original research proposal. Under VA regulations, the agency must apply the same project (nonfinancial) controls to research sponsored by drug

[1]A VA-administered trust fund that is a depository for donations from private citizens and organizations, including veterans' groups and drug companies.

companies and other outside organizations as it does to research it sponsors.

Use of Drug Company-Donated Funds Legal

VA has authority to accept donations and to use donated funds as directed by the donor when the use is for the benefit of veterans. It is reasonable to conclude that the medical research in question benefits veterans. In light of this conclusion and VA's statutory mandate to conduct a medical research program, the use of drug company-donated funds for medical research does not constitute an improper supplement to VA's appropriations.

Need for Improved VA Guidelines for Receiving Drug Company Research Funds

VA needs to revise its guidelines concerning the receipt of drug company funds that are administered by outside institutions (VA-affiliated medical schools or university foundations) to assure that sponsors know that payments are not to be made directly to individual VA investigators. About 35 percent of the funds donated to VA directly by drug companies are deposited in the General Post Fund and administered by the medical center at which the research will be conducted. The other 65 percent are provided to outside institutions even though the studies are performed at a VA facility.

VA guidelines require that all payments connected with medical research studies be made to the General Post Fund or an outside institution approved by a VA medical center research and development committee. The guidelines also require the directors of VA medical centers to instruct outside sponsors, including drug companies, to make donations intended for the General Post Fund directly payable to VA. The guidelines, however, are silent as to whether medical center directors should instruct sponsors to make checks payable to outside institutions when the funds are to be deposited in the accounts of such institutions for research conducted in VA medical facilities. VA considers medical research performed in its facilities to be part of the investigators' official VA duties. Federal employees are prohibited from supplementing their salaries with funds received from private sources, if such funds are compensation for the individual's services to the government. According to the VA Office of Inspector General, two VA research investigators in 1984 improperly received funds directly from outside sponsors—one a drug company.

Accounting Systems Do Not Tell Whether VA Recovers Costs for Drug Company-Sponsored Research

VA laws and regulations do not state that the agency should recover costs it incurs for research studies sponsored by outside organizations. None of the three VA medical centers we visited had an accounting system capable of disclosing whether they were receiving sufficient funds to cover the costs of drug company-sponsored research. Therefore, we could not determine whether VA recovers all of its costs.

Investigations of Long Beach VA Medical Center Research Activities

In addition to Dr. Wilbert S. Aronow, VA investigated 13 other VA medical research investigators at the Long Beach Medical Center who allegedly accepted unauthorized remuneration from drug companies to do research in VA facilities or conducted research studies not authorized by VA. Five of these allegations were sustained—that is, substantiated or proven to be valid. In particular:

1. We reviewed a 1974 VA investigation report involving a procedure performed during medical research studies conducted by Dr. Aronow and allegations that he had not fully informed his research subjects of the purposes and adverse effects of the procedure. We concluded that VA's overall actions in response to this part of the investigation report were reasonable and effective. The VA investigators also examined Dr. Aronow's alleged falsification of research data. Because detailed VA documentation of these matters was unavailable, however, we could not determine whether the agency should have taken additional action.

2. Of Dr. Aronow's 149 coauthors, 8 were investigated by the VA Office of Inspector General for allegedly accepting unauthorized remuneration from drug companies in violation of VA guidelines. Allegations against three of the coauthors were sustained, and VA took appropriate administrative or legal actions.

3. Five other Long Beach Medical Center medical researchers who were not Dr. Aronow's coauthors were investigated by the Inspector General because of allegations that they had received unauthorized remuneration from drug companies or conducted unauthorized research studies. The allegations against two of the researchers were sustained, and VA initiated appropriate administrative or legal actions.

Recommendations to the Administrator of Veterans Affairs

We recommend that the Administrator direct the Chief Medical Director to revise VA's guidelines to require VA medical center directors to inform outside sponsors of research, including drug companies, before studies are initiated in VA medical facilities that

- the studies will be performed by VA investigators as part of their official VA duties,
- federal law prohibits all VA employees from receiving compensation from outside the agency for services performed in connection with their official VA duties and prohibits anyone from providing such compensation, and
- all payments in connection with the studies should be made to the General Post Fund or an outside institution approved by a VA medical center research and development committee, and not to individual VA investigators.

We discussed our findings with VA officials and have included their comments where appropriate. As requested by your office, however, we did not obtain the views of agency officials on our conclusions and recommendations or request official agency comments on a draft of this report.

Details on our objectives, scope, and methodology are included in appendix II. Except as noted there, our review was conducted in accordance with generally accepted government auditing standards.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time we will send copies to VA and other interested parties and make copies available to others upon request.

Sincerely yours,

Richard L. Fogel
Director

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Abbreviations

ACMD/R&D	Assistant Chief Medical Director for Research and Development
ACOS/R&D	Associate Chief of Staff for Research and Development
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
OIG	Office of Inspector General
R&D	Research and Development
RDIS	Research and Development Information System
VA	Veterans Administration

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Drug Company-Sponsored Research at VA Medical Facilities

Based on a request by the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, and later agreements with his office, we reviewed the five aspects of drug company-funded research in Veterans Administration (VA) medical facilities presented on page 1.

VA Research Involvement With Drug Companies

VA's research and development program supports the agency's efforts to provide high-quality medical care for eligible veterans. According to VA documents, during fiscal year 1984 about 6,000 VA investigators, whose primary responsibility was to provide patient care, worked on about 10,000 research studies.

Enactment of Public Law 79-293 in 1946 gave a major impetus to VA medical research. Among other provisions, this law, as amended, committed VA to a program of affiliations with U.S. medical schools whenever feasible and prudent. By helping to attract physicians who were interested in combining medical research and teaching with clinical practice, the affiliation programs fostered the growth of medical research within the VA health care system. The opportunity to receive medical research funding became an important factor in VA's recruitment of physicians.

As of September 1985, most VA medical centers were affiliated with medical schools. The centers are, therefore, often staffed by physicians who are also on the faculty of an affiliated medical school. In addition to providing patient care to veterans, these physicians supervise the medical centers' residents and interns and conduct medical research. VA is authorized under 38 U.S.C. 5051 (1982) to enter into agreements with medical schools to share space, equipment, and personnel in order to effectively use other medical resources in the surrounding community. For example, medical schools may reimburse VA medical centers for the use of specialized laboratory equipment and radiological services, or physician specialists may divide their time in providing patient care between a VA medical center and an affiliated medical school.

At least 715 drug company-financed studies were carried out in at least 81 VA medical centers in fiscal year 1984, the latest period for which data were available at the time of our review. These studies represent 7 percent of the 10,000 studies conducted by VA investigators.

Drug companies provided at least $26.6 million to support VA research through VA's General Post Fund and the accounts of VA-affiliated medical

schools or university foundations. Funds deposited in the General Post Fund are administered by the VA medical center that received the donation. The affiliated medical schools or university foundations administer funds deposited to their accounts. As most studies are approved for more than one fiscal year, not all funds are spent in the year received. The distribution of medical research studies and funds received from drug companies between the General Post Fund and outside institutions is shown in table I.1.

Table I.1: Drug Company-Funded Research Reported at 81 VA Medical Centers for Fiscal Year 1984

	Funds administered through		
	VA General Post fund	Outside institutions[a]	Total
Number of studies	336	379	**715**
Funds received	$9,410,396	$17,239,090	**$26,649,486**

[a]Includes VA-affiliated medical schools and university foundations

Based on information we obtained from VA's central office, VA's automated Research and Development Information System (RDIS) data on the number of research studies and amount of funding obtained from drug companies were incomplete or not readily available for 44 of the 81 VA medical centers that reported conducting drug company-sponsored medical research during fiscal year 1984. Consequently, drug company-sponsored research, as shown in table I.1, is understated.

The Deputy Assistant Chief Medical Director for Research and Development (Deputy ACMD/R&D) stated that the primary benefit to VA from its research involvement with drug companies is the opportunity for veterans to obtain early access to new drugs. This official stated that new drugs tested in VA medical centers are oriented toward treating diseases prevalent among veterans, such as hypertension and certain types of cancer. When conventional drug therapy has been unsuccessful, patients have a strong incentive to volunteer for the studies.

Research officials at the Long Beach, Madison, and East Orange Medical Centers said that VA also benefits from drug company-sponsored research because drug companies—in contrast to the National Institutes of Health and most nonprofit health organizations (e.g., the American Heart Association)—often provide more funds than needed for their research studies and generally do not restrict the use of the excess funds. Drug company officials told us that their funds may be used for research activities unrelated to the companies' sponsored studies, as

long as VA investigators carry out specific studies related to the companies' development of new drugs as specified in the protocols (descriptions of research objectives and methods). VA research officials confirmed that VA investigators use drug company funds to carry out studies that the companies sponsor and to help finance other studies that the investigators consider to be underfunded, such as those sponsored by the National Institutes of Health or the VA central office.

VA officials said that the excess drug company funds, regardless of where deposited and administered, may also be used by investigators to pay for travel to medical conferences, subscriptions to medical journals, and other items that will benefit the overall research program. According to the Associate Chief of Staff for Research and Development (ACOS/R&D) at the Madison Medical Center, access to an external source of discretionary research funds gives investigators a strong incentive to work on drug company-sponsored studies. This is especially so because in recent years increased competition among investigators for other major sources of research funding, such as National Institutes of Health grants, has made those funds more difficult to obtain.

Reasons Drug Companies Sponsor VA Studies and Impose Conditions

Drug companies finance VA research to test their new drugs on VA patients in clinical settings, according to drug company officials with whom we met. Among the major reasons cited were the expertise of VA investigators and certain characteristics of VA's patient population. For example, the Vice-President for Clinical Research at E.R. Squibb and Sons, Inc., told us that a major factor in Squibb's involvement with VA is the firm's development of new drugs to treat hypertension. Because VA medical centers have investigators with expertise in hypertension and many patients with the disease, the centers are ideal settings for testing new anti-hypertensive drugs.

The drug companies usually develop the research protocols so that they comply with testing requirements of the Food and Drug Administration (FDA), which regulates the testing and marketing of all new drugs in the United States. Consequently, drug companies usually impose conditions on VA, such as being allowed to review all study data, to ensure that VA investigators have complied with the companies' protocols and FDA's requirements.

Typically, a drug company begins to develop a new drug by screening large numbers of chemical compounds in laboratory animals for possible therapeutic results. It selects the most promising compounds for further

study and applies to FDA to begin testing those compounds in humans. In this investigational drug application, the company describes the closely controlled clinical tests it will conduct to determine the new product's safety and efficacy. If the application is approved, the sponsor selects VA investigators or other medical researchers to carry out the protocol.

VA research officials and drug company officials told us that drug firms usually identify specific VA investigators through their contacts in the scientific community or by reviewing the medical literature to determine which investigators have expertise in subjects relevant to the companies' drug research.

When drug companies arrange with VA investigators to sponsor research projects, they usually impose certain conditions. Normally these conditions are stated in study protocols the company provides, although they may also be described in written correspondence or communicated orally to the investigators. For example, the sponsor may require VA investigators to

- obtain drug company approval before changing study protocols,
- allow the drug company to review journal articles describing the results of the study before publication, and
- facilitate FDA's and/or the company's access to research study records to assess the validity of data.

These conditions are intended to ensure that investigators follow the steps described in the protocols and comply with FDA requirements for drug studies.

After completing clinical tests, the drug company may file with FDA a new drug application which, if approved, permits the sponsor to market the drug.

VA's Nonfinancial Controls for Drug Company-Sponsored Studies

Before VA investigators begin any research studies, including those sponsored by drug companies, they are required to submit research proposals to the Research and Development (R&D) committee of the VA medical center at which the study will be conducted. All studies, regardless of sponsorship, are subject to the same nonfinancial controls. The R&D committee comprises senior VA clinical staff and faculty of affiliated universities. It monitors study progress, must approve major changes to the original proposal, and plays a major role in deciding which proposals

have scientific merit and are consistent with VA's research mission. Subcommittees review other aspects of research proposals, such as protection of human subjects.

In addition, studies that propose the use of VA-administered, congressionally appropriated funds for specialized equipment and other resources must be reviewed by the VA central office. According to VA data, during fiscal year 1984 about 3,000 of the 10,000 VA research studies were reviewed by the central office. The other 7,000—including most drug company-sponsored studies—did not involve VA-administered, congressionally appropriated funds or specialized research resources.

Research officials at the Long Beach, Madison, and East Orange VA Medical Centers said their R&D committees do not approve drug company-sponsored studies solely because additional research funding is available. The investigators must also demonstrate to the committees that the studies have scientific merit and will benefit veterans.

Human studies subcommittees of R&D committees evaluate VA research proposals that involve human subjects. VA guidelines state that a subcommittee may not approve a research study if the anticipated benefits of the proposed study do not outweigh the risks to human subjects. According to research officials at the three VA medical centers we visited, drug company-sponsored studies pose few risks to participating VA patients because the studies involve drugs that are in the final stages of clinical testing, after potential side effects usually have been identified. Generally, the officials noted, drug company-sponsored studies do not require patients to make additional hospital visits or to undergo tests and procedures beyond those normally required for their medical treatment.

Monitoring of Drug Company-Sponsored Research

Like most university researchers, VA investigators have a great deal of autonomy in conducting their studies. After a VA study is initiated, the investigator is responsible for insuring that the research is performed as described in the protocol. The R&D committee, however, is to monitor the investigator's progress and approve changes to the protocol. When the study is completed, the investigator is to submit a report to the committee for review.

In addition, FDA may review VA medical research studies when they are included in drug companies' investigational drug applications. In

November 1983, VA and FDA signed a memorandum of understanding to facilitate communication and encourage cooperation concerning investigational drug research. This agreement, revised in November 1984, is intended to assure the protection of VA human subjects and the validity of data in VA studies submitted to FDA. In it,

- VA agrees to facilitate FDA's access to administrative records and patient medical records associated with any investigational new drug, and
- FDA agrees to promptly advise VA if any investigator's research is not carried out as called for in the protocols or generally accepted research standards.

VA Investigators May Not Neglect Patient Care Responsibilities

VA investigators are expected to devote most of their efforts to patient care unless they are participating in the Career Development Program.[1] VA has no formal guidelines, however, on how much time an investigator should devote to research, patient care, and other duties. According to the Deputy ACMD/R&D, it is difficult to distinguish between most investigators' research and patient care activities because the two are closely related. For example, investigators often provide treatment to patients as part of a research protocol. To assure that VA investigators do not neglect patient care, VA medical center R&D committees are to review investigators' clinical, research, and academic activities annually.

Research officials at the VA central office and the three medical centers we visited believe that the chances of an investigator neglecting patient care duties in favor of drug company-sponsored research is small, because those who engage in research must obtain the approval of their clinical service chiefs. If a service chief finds an investigator neglecting patient care duties, VA officials told us, that investigator's research activities will be curtailed.

Use of Drug Company-Donated Funds Legal

The Administrator of Veterans Affairs is authorized under 38 U.S.C. 5101 (1982) to accept "devises, bequests, and gifts" for the benefit of veterans who are patients or residents at facilities operated by the United States or for the benefit of such facilities. The law requires donated funds to be deposited with the Treasurer of the United States to the credit of VA's General Post Fund.

[1]This program exempts selected VA clinicians from most patient care responsibilities so they can devote about 75 percent of their time to research activities during a specific period. As of July 1984, nationwide, about 185 investigators were participating in this program.

Disbursements from the General Post Fund under 38 U.S.C. 5223 (1982) must be for the benefit of patients while they are receiving VA medical care or treatment in any facility or hospital. Under 38 U.S.C. 5103 (1982), VA has some discretion in making disbursements from the Fund. However, funds contributed to the General Post Fund with specific directions for their use by the donor are to be used as directed, as long as such use is authorized under the provisions of law establishing the Fund. (38 U.S.C. 5101-5105 (1982))

Under 38 U.S.C. 5101-5105, donated funds may be used for the benefit of veterans who are patients in VA facilities or for the benefit of the facilities. Also, 38 U.S.C. 4101(c) (1982) mandates the Administrator to conduct a program of medical research in connection with the provision of medical care and treatment to veterans.

VA central office research officials stated that the research conducted at VA medical centers as a result of drug company donations benefits veterans because it involves the testing of new drugs that could immediately or ultimately benefit patients in VA facilities. VA believes that such donations also benefit VA's ongoing medical research and development program. We believe that VA's determination is reasonable. In light of both the reasonableness of VA's determination and its statutory mandate to conduct a medical research program, VA's use of donations for research specified by the donors is authorized by law.

The rule regarding augmentation of appropriations is that an agency may not augment its appropriations with funds from outside sources without specific statutory authority. Since VA has the requisite statutory authority, the donations in question would not constitute an improper supplement to VA's appropriation.

Need for Improved VA Guidelines for Receiving Drug Company Research Funds

VA's guidelines require the directors of VA medical centers to instruct outside sponsors, including drug companies, to make donations intended for the General Post Fund directly payable to VA. The guidelines, however, are silent as to whether medical center directors should instruct sponsors to make checks payable to outside institutions, like affiliated medical schools or university foundations, when the funds are to be deposited in the accounts of such institutions for research conducted in VA medical facilities. Consequently, VA has no assurance that sponsors know that such funds must be deposited in medical school accounts and not provided directly to individuals for their work as VA investigators, which is prohibited by federal law. According to the VA Office of

Inspector General (OIG), two individual research investigators in 1984 improperly received funds directly from outside sponsors—one a drug company.

In a 1984 report,[2] we discussed VA's actions to improve controls over donations received by VA to support research and deposited in the General Post Fund. VA's revised guidelines, issued in May 1984, were intended to assure that VA medical centers informed drug companies and other potential donors of VA requirements. In particular, the guidelines stipulated that:

- Donations for research were to be made payable to VA.
- Prior approval of the VA medical facility's R&D committee and director was required before donations were accepted.
- In written acknowledgements of donations or proposed donations, the donor was to be informed of VA's policies and procedures for receiving and using donations. The guidelines also suggested sending the donor a copy of the revised guidance.

We concluded in our 1984 report that while these guidelines might not prevent donors, such as drug companies, from making payments directly to VA research staff, they made it clear that such payments are improper. Based on our current review and the January 1986 OIG report, VA's guidelines should be improved to help prevent improper payments to VA research staff.

Most Drug Company Funds Are Not Deposited in the General Post Fund

According to research officials at the three medical centers we visited, generally drug company-sponsored studies involving VA investigators and patients are conducted at VA facilities regardless of whether the agency or an affiliated medical school received the funds. The officials also said that VA medical center R&D committees allow VA investigators to decide whether drug companies' funds should be deposited in the General Post Fund or in accounts of the non-VA institutions.

Of the $26.6 million drug companies donated to support research studies at VA medical centers in fiscal year 1984, $17.2 million was received and administered by outside institutions. These funds were not deposited to the VA General Post Fund. VA investigators have more discretion in

[2]Status of EPA's Air Quality Standards for Carbon Monoxide (GAO/ RCED-84-201, Sept. 27, 1984). This report discussed the medical research activities of Dr. Wilbert Aronow, who also conducted medical research under the auspices of VA and FDA (see pp. 23 to 30, herein).

deciding how funds are used when they are not deposited to the General Post Fund.

Research officials at the three VA medical centers we visited told us that restrictions on travel and hiring at VA have influenced investigators to steer drug company research funds to VA-affiliated medical schools. The ACOS/R&D at the Long Beach VA Medical Center told us that, because of VA restrictions on travel and hiring of personnel in recent years, he has encouraged investigators at his facility to ask that drug company research funds be channeled through the affiliated medical school, rather than the General Post Fund. The medical school, he said, has fewer restrictions than VA on hiring and travel in relation to research.

We reviewed Long Beach Medical Center records to determine if drug company funds deposited in General Post Fund research accounts had decreased in recent years. We found that $35,507 was received in fiscal year 1984, compared to $89,800 in fiscal year 1980. The ACOS/R&D at Long Beach confirmed that over that period VA investigators increasingly steered drug company research funds to the affiliated medical school and the decrease in donations deposited in the General Post Fund reflected this shift. Research officials at the Madison and East Orange VA Medical Centers told us there were similar shifts away from the Fund to the affiliated institutions in recent years.

OIG Audit of Controls Over Funds Provided for Medical Research

After auditing four VA medical centers, the OIG concluded in a January 1986 report[3] that they generally had adequate controls over funds donated to VA and maintained in the General Post Fund. But none of the four centers audited by the OIG (these medical centers were not included in our review) had adequately complied with policies pertaining to funds administered by non-VA entities (medical schools affiliated with the VA medical centers). Accordingly, the OIG recommended that:

1. The VA Chief Medical Director require medical center management and R&D committees to develop procedures to insure compliance with VA policies pertaining to extra-VA research funds. These procedures should ensure that (a) researchers report all extra-VA funds offered; (b) medical center directors review and approve all research funds, including funds

[3] Audit of Controls Over Extra-VA Research Funds (VA/OIG 6R8-A09-036, Jan. 28, 1986). Extra-VA research funds are provided by private corporations, charitable foundations, and government agencies to support the VA medical research program. These funds are called extra-VA funds by the OIG to distinguish them from appropriated funds.

to be administered by non-VA entities, offered to researchers at their centers; (c) extra-VA funds be administered only by medical centers or approved non-VA entities that agree to provide an accounting of the funds received and expended; (d) the use of extra-VA funds be specifically related to the research project or purpose for which the funds were provided; and (e) R&D committees consider the availability of extra-VA funding when allocating appropriated funds and other resources to individual research projects.

2. R&D officials monitor medical center compliance with VA policies pertaining to extra-VA funds through periodic site visits or peer reviews.

The Chief Medical Director generally concurred with the recommendations, and the OIG reported that the following actions were taken:

- VA's Department of Medicine and Surgery issued an instruction citing the results of the OIG audit and emphasizing that researchers must report extra-VA funding and that R&D committees must comply with all requirements pertaining to the control of such funding.
- VA central office R&D staff were instructed to continue to monitor medical center compliance with VA policies and procedures through Research Advisory Committees' routine and special purpose site visits, the merit review process and merit review site visits, and review of R&D committee minutes.

The OIG reported that the above actions were acceptable.

Improved Guidelines Needed to Help Prevent Inappropriate Payments to VA Research Investigators

We concur with the OIG that compliance with VA policy—as recommended in the January 1986 report—should provide adequate control over funds deposited in the accounts of outside institutions. We believe, however, that VA should also require its medical center directors to instruct research sponsors to make their payments to outside institutions when the funds are not deposited in the General Post Fund. This would help assure that such funds are not given directly to investigators as has occasionally happened.

Federal employees are prohibited by 18 U.S.C. 209 (1982) from supplementing their salaries with funds received from private sources, if such funds are compensation for the individual's services to the government. The same law also prohibits giving such compensation. VA considers research studies performed in VA facilities to be part of the investigators' official duties.

Differences in Procedures in Administering Drug Company Research Funds That Were Deposited in Non-VA Accounts

Regarding drug company funds deposited in non-VA accounts, the three medical centers we visited had different administrative procedures. Research officials at the three centers told us that the VA investigators decided whether to deposit drug company research funds in the General Post Fund or an outside institution's account. VA's RDIS data showed that, during fiscal year 1984, at least $1.5 million was provided by drug companies in support of research at the Long Beach, Madison, and East Orange VA Medical Centers. Of this amount, about $1.2 million was deposited in outside institutions.

Research officials said that when VA investigators submitted proposals to the R&D committees to conduct drug company-sponsored studies, the investigators would inform the committees of the funding expected. The officials stated that investigators were responsible for telling the companies where to send the funds.

During our visits to the three VA medical centers, we found that the R&D committees differed in documenting funding arrangements made by investigators with drug company sponsors, as follows:

- The Madison R&D committee did not contact drug companies to verify the channeling of funds investigators had arranged with the companies.
- The East Orange R&D committee required drug companies to inform it in writing about funding arrangements before initiating the research study, but only if the investigator had told the committee that the donation was to be deposited in the General Post Fund. The committee did not require the sponsors to confirm the arrangements for channeling funds to non-VA institutions.
- The Long Beach R&D committee required investigators to submit to the committee, before initiating drug company-sponsored studies, a signed statement from the company indicating how much funding would be provided and where it would be deposited, whether in the General Post Fund or in an outside institution.

At all three facilities research officials said that their present controls did not ensure that research funds would not be given directly to individual investigators.

The January 28, 1986, OIG report discussed improper remuneration received by two research investigators at the West Los Angeles VA Medical Center. These two full-time VA employees were included in the audit after private corporations—one a drug company—informed the OIG that payments had been made directly to VA investigators. The OIG concluded

that neither investigator obtained proper authorization to accept the remuneration and both may have received the remuneration illegally because the services for which they were paid may have been performed in the course of their official VA duties. As of February 1986, these cases were under further investigation by the OIG.

Drug Companies Rely on Investigators for Guidance on Distribution of Funding

Officials from the three drug companies we visited—Squibb, Pfizer, and Hoffmann-LaRoche—told us that they relied entirely on investigators for instructions on where to send research funds. VA's RDIS data showed that, during fiscal year 1984, at least 51 VA medical centers conducted studies funded by these three firms.

Officials at Squibb and Hoffmann-LaRoche stated that VA medical center officials generally did not contact them to verify funding arrangements made by investigators. According to a Pfizer official, his firm required VA investigators to sign an agreement that described how funds would be distributed, but the investigator decided whether a VA medical center official cosigned the agreement and, if so, which official.

Officials at all three firms recalled situations in which their companies, at the request of VA investigators, issued checks payable to investigators. The Vice President for Clinical Research at Squibb and a Senior Corporate Counsel at Pfizer both stated that their research officials were unaware that issuing checks directly payable to investigators was contrary to VA guidelines or that VA expected all funds for drug studies to be used exclusively for research activities. A company attorney stated however, that Hoffmann-LaRoche officials had been apprised of VA guidelines prohibiting direct payments to investigators.

Conclusion

VA has issued guidelines concerning financial controls over research funds donated to VA and deposited in the General Post Fund. However, VA guidelines do not address whether medical center directors are to instruct research sponsors to make their payments to outside institutions when the funds are not deposited in the General Post Fund. Therefore, in these cases there is no assurance that checks are issued to VA-affiliated medical schools or university foundations—which administer research funds not deposited in the General Post Fund—and not to individual VA investigators, which is prohibited by federal law.

Recommendations

We recommend that the Administrator of Veterans Affairs direct the Chief Medical Director to revise VA's guidelines to require VA medical center directors to inform outside sponsors of research, including drug companies, before studies are initiated that

- the studies will be performed by VA investigators as part of their official VA duties;
- federal law prohibits all VA employees from receiving compensation from outside the agency for services performed in connection with their official VA duties and prohibits anyone from providing such compensation; and
- all payments made in connection with the studies should be made to the General Post Fund or an outside institution approved by a VA medical center R&D committee, and not to individual VA investigators.

Accounting Systems Do Not Tell Whether VA Recovers Costs for Drug Company-Sponsored Research

Statutes applicable to VA and VA regulations and guidelines do not address whether the costs incurred by the agency for research studies sponsored by outside organizations should be recovered. None of the accounting systems at the three medical centers we visited could disclose whether funds received from drug companies for research were sufficient to cover VA's costs related to the research. Consequently, at these centers we could not determine whether VA recovered all costs involved in performing such research.[4]

All Research Costs Are Not Paid From R&D Funds

VA central office officials told us that as long as drug company-sponsored research studies are judged by the medical centers' R&D committees to benefit veterans and meet other VA criteria, appropriated funds may be used to help finance the studies. VA guidelines prohibit using R&D funds for administrative support services; e.g., radiation safety and infection control. Also, VA investigator salaries generally may not be paid from R&D funds. As a result, VA does not expect total costs of research to be paid from R&D funds.

[4]We found similar inadequacies among other VA financial management systems as reported in Veterans Administration Financial Management Profile (GAO/AFMD-85-34, Sept. 20, 1985).

Costs for Individual Research Studies Cannot Be Identified

VA central office officials told us that because VA does not require all research costs to be paid out of research funds, medical centers need not keep track of all such costs.

None of the three medical centers we visited employed a cost accounting system capable of identifying total direct and indirect costs related to individual research studies. Direct costs include salaries of staff directly engaged in research, materials and supplies consumed, special equipment purchased, and other costs incurred specifically for a particular study. Indirect costs include expenses for common resources shared by research investigators (e.g., laboratory facilities, data processing, and research program administration) and other costs not directly attributable to specific studies.

Financial Benefits From Drug Company-Sponsored Studies

According to drug company officials, the funding that their firms provide for medical research is generally expressed in terms of a specific dollar amount for each VA patient completing the research study. Funding levels for VA research studies, they said, are influenced primarily by the amounts the drug companies are providing for similar studies in non-VA facilities, rather than on the costs VA will incur to conduct the studies.

Data on costs and benefits associated with drug company-sponsored studies were not compiled at the three VA medical centers we visited. However, research officials at these centers believed the financial benefits to VA's research program from drug company-sponsored studies significantly exceeded VA's costs. The financial impact of drug company-sponsored studies on the medical centers is discussed during R&D committee evaluations of research proposals, according to center officials. They require investigators to present sufficient information in their research proposals to assure that VA will recover the significant costs related to the research studies. Also, by reviewing research protocols, R&D committee members can determine the resources needed to carry out the studies, the officials said. The study protocol identifies the number of patients in the study and the number and kinds of tests or procedures involved. None of the three VA facilities, however, had a written policy concerning this issue.

Financial Impact on Nonresearch Departments

Research officials at the three medical centers in our review said that generally drug company-sponsored research studies do not require patients to make clinic visits or to be subjected to medical procedures—

such as laboratory tests or X-rays—in addition to those required as part of their routine medical treatment. Therefore, departments responsible for patient care services would not incur additional costs when VA investigators conducted drug company-sponsored studies in these departments, the officials explained.

Drug company-sponsored studies, however, may add extra costs to medical center pharmacy operations. The chiefs of pharmacy services at all three VA medical centers told us that investigational drug studies cost the pharmacies additional staff time to control drug supplies, help investigators collect data, and maintain various records required by FDA and VA.

The pharmacy services differed in efforts made to keep track of or recover the additional costs related to drug company-sponsored studies. At the Madison VA Medical Center, the chief of the pharmacy service told us that drug company funds in the General Post Fund and the affiliated medical school account were charged for the salary of a research pharmacist who spent all of his time on drug company-sponsored research studies. We noted that in the second quarter of fiscal year 1984, each account was charged $2,100 for this pharmacist's salary. The chiefs of the pharmacy service at the other two medical centers told us they did not attempt to keep track of or recover additional costs incurred for research activities.

Conversely, the pharmacy services may benefit financially from drug company-sponsored research because they receive supplies of new investigational drugs to use in the studies. According to VA research officials, donated investigational drugs used in research studies often serve as substitutes for drugs that the medical centers would otherwise purchase and prescribe for patients.

At the East Orange VA Medical Center we found a research study for which drugs were supplied to 21 patients participating in a study that involved a new antibiotic used to treat skin infections. A pharmacist at East Orange estimated VA saved over $2,000 by using drugs donated by the drug company sponsor instead of purchased drugs.

Conclusion

Statutes applicable to VA and VA regulations and guidelines do not address whether VA should recover the costs incurred for research studies sponsored by outside organizations. Also, without accurate and

complete cost accounting data, VA cannot determine the costs of performing drug company-sponsored research studies.

Investigations of Long Beach VA Medical Center Research Activities

We reviewed a 1973 VA investigation of a cardiac catheterization[5] research procedure of Dr. Wilbert S. Aronow[6] and the allegations that he had not fully informed his research subjects of the purposes and possible adverse effects of the procedure. We concluded that VA's actions in response to this part of the investigation were appropriate and effective.

The investigation report also discussed other aspects of Dr. Aronow's research practices. However, because detailed documentation was not available, we were unable to determine whether VA's actions were appropriate and effective.

In addition, we found that 8 of Dr. Aronow's 149 coauthors (1973 to 1982) were investigated by the OIG for allegedly accepting unauthorized remuneration from drug companies in violation of VA guidelines. Allegations in three of these cases were sustained (that is, substantiated or proven to be valid) and VA took appropriate administrative and/or legal action to admonish these individuals.

We also identified five other VA investigations of Long Beach VA Medical Center researchers, who were not Dr. Aronow's coauthors, involving allegations that they had received unauthorized remuneration from drug companies or conducted unauthorized research studies. Allegations against two of the researchers were sustained, and VA took appropriate administrative and/or legal action.

[5]In cardiac catheterization, a thin, pliable tube—the catheter— is inserted into an incision in the patient's arm or groin and passed through a vein or artery into the heart chambers. The procedure is usually used to diagnose heart ailments.

[6]Dr. Aronow was a full-time VA employee who was chief of the cardiovascular section at the Long Beach Medical Center. While employed at Long Beach, Dr. Aronow was investigated by FDA for alleged falsification of drug research results and by VA for, among other things, receiving outside remuneration from drug companies. In 1983, a panel of experts assembled by the Environmental Protection Agency (EPA) expressed concern about the validity of studies conducted by Dr. Aronow at VA that were the basis of certain EPA clean air standards. He resigned in March 1982 while VA was in the process of removing him from employment for unauthorized receipt of money from drug companies. We previously reported on these matters in Status of EPA's Air Quality Standards for Carbon Monoxide (GAO/RCED-84-201, Sept. 27, 1984).

VA's 1973 Investigation of Dr. Aronow

VA's 1973 investigation concentrated on Dr. Aronow's use of cardiac catheterization in research studies and the allegation that he had not fully informed his research subjects of the purpose and possible adverse effects of this procedure. VA's actions to remedy these problems appeared reasonable and effective.

The VA investigation also raised questions concerning Dr. Aronow's alleged falsification of research data and suggested that the Long Beach VA Medical Center adopt appropriate controls to assure that the quality of his patient care not be compromised by his research activities. No formal recommendations, however, addressed these matters. As far as we could determine, neither the investigation report nor any other information on Dr. Aronow's development and use of research data was provided to Long Beach Medical Center officials.

VA guidelines require investigators to fully inform potential research subjects concerning the study and the planned use of drugs and/or procedures, including possible adverse reactions. Moreover, VA guidelines require investigators to obtain prior written consent of patients who participate in a research study.

Questions concerning Dr. Aronow were first raised on August 27, 1973, when Long Beach's Human Studies Subcommittee met primarily to discuss a patient who that month had suffered a major cerebrovascular accident following a cardiac catheterization done as part of a study Dr. Aronow conducted. The subcommittee concluded that (1) the patient had been a study subject 2 months before the center's R&D committee approved the study, (2) Dr. Aronow had not obtained the informed consent of the patient to participate in the research study, and (3) Dr. Aronow had not accurately described the possible complications of cardiac catheterization to the R&D committee.

In October 1973, the ACMD/R&D began investigating the participation of patients and others as subjects in clinical research studies at the Long Beach VA Medical Center. Particular attention was focused on Dr. Aronow's use of cardiac catheterization. A report was issued on January 4, 1974.

In addition to the August 1973 incident described above, the report discussed a September 13, 1973, incident at the medical center in which a

patient died about 5 hours after cardiac catheterization had been performed as part of a different research study.[7] The ACMD/R&D's report concluded that the complications experienced by the first patient following cardiac catheterization probably would have occurred even had he not participated in the research study. The report stated that the second patient's autopsy report did not relate the cause of death to any direct effect of the catheterization procedures.

But procedures performed at the Long Beach VA Medical Center for clinical care, according to the report, were not clearly distinguished from those for research purposes, as required by VA guidelines. In addition, the report expressed concern that patients participating in research studies were not systematically and completely informed about research procedures and questioned the facility's research review procedures.

VA Central Office Response To Cardiac Catheterization Incidents

Before the ACMD/R&D's report was released, however, the VA central office directed the Long Beach Medical Center's Chief of Staff to discontinue all cardiac catheterizations, pending a central office review. This directive was contained in an October 19, 1973, letter that confirmed an earlier oral communication. Although the ACMD/R&D report indicated that the center may have discontinued cardiac catheterization for research purposes as early as September 1973, we were unable to determine the exact date of the oral communication.

The Director of VA's Western Region, in a November 1, 1973, letter to the Long Beach Medical Center Director, outlined what the medical center had to do before it resumed cardiac catheterization for research purposes:

1. Develop guidelines for cardiac catheterization that clearly distinguished between procedures performed for clinical purposes and those carried out for research purposes.

2. Increase and document supervision of all cardiac catheterization.

3. Reconstitute the R&D committee to include several members with no direct personal interest in the research.

[7]The August 1973 incident involved the testing of an investigational drug for the treatment of hypertension, while that of September 1973 involved a study of the effect of cigarette smoking on certain coronary functions.

4. Assure that research protocols explain in detail patient selection, the plan of study, techniques to be used, risks involved, and the ultimate expected benefits.

On May 24, 1974, VA's Chief Medical Director, in confirming these requirements, informed the Long Beach Medical Center Director that cardiac catheterization for research purposes could not be resumed until he provided written assurance that the Regional Director's requirements had been complied with and furnished written evaluations of all studies involving cardiac catheterization. Furthermore, there was to be a review by non-VA authorities of questionable research protocols involving cardiac catheterization before the R&D committee took final action.

In October 1974, the Chief Medical Director informed the Long Beach Director that because the above requirements had been satisfied, the center could resume cardiac catheterization for research purposes.

Other Concerns About Dr. Aronow's Research Activities

Other observations about Dr. Aronow's research practices in the ACMD/R&D's January 4, 1974, report included:

"It must be stated that he is not 'self-policing' and tends to use available scientific data in that manner which is most likely to support his preconceived plan of action."

The report did not make the meaning of this statement clear, but suggested that the Long Beach Medical Center adopt appropriate supervisory controls over Dr. Aronow to assure that the quality of his patient care was not compromised by his research activities.

In April 1985, the former ACMD/R&D who prepared the report told us that he did not recall any information from his 1973 investigation that Dr. Aronow was falsifying research findings or engaging in misconduct other than that related to obtaining patient consent for research purposes. The official agreed, however, that he probably would have made such a damaging statement only if he were concerned about the reliability of Dr. Aronow's research.

Also, the former ACOS/R&D at the Long Beach Medical Center told us in April 1985 that neither he nor any other Long Beach research officials received copies of the ACMD/R&D's January 1974 report. As a result, they were not aware of the concern expressed about Dr. Aronow's research practices. The same official told us that following the October 1973

investigation, the center's R&D committee informally reviewed Dr. Aronow's research practices, examining several of his research projects for proper completion of patient consent forms and other paperwork. No new problems were identified.

OIG Investigations of Dr. Aronow's Coauthors

We identified 149 individuals who coauthored scientific medical articles with Dr. Aronow between 1973 and 1982. Of these, eight had been investigated by the OIG for allegedly accepting unauthorized remuneration from drug companies in violation of VA guidelines.[8] All eight coauthors were employed as Long Beach Medical Center physicians. Allegations against three of the coauthors were sustained.

Investigations of Eight Coauthors Concerned Unauthorized Outside Remuneration

The investigations of the eight coauthors, part of the OIG's investigation of Dr. Aronow from November 1980 to April 1981, focused on allegations of unauthorized remuneration. Five allegedly had received $64,300 in payments directly from drug companies, in amounts ranging from $500 to $37,100. The OIG report did not specify the amounts for the other three.

Allegations against three of the coauthors were sustained, according to information provided by the OIG. For one of the three, VA drafted a proposed letter of removal, but the employee resigned before the personnel action was completed. The other two employees resigned before VA initiated personnel actions.

The sustained allegations involved improper receipt of $25,700 in payments from drug companies. VA disclosed the names of these three individuals when it referred Dr. Aronow's case to the Department of Justice. Justice declined to prosecute them on the grounds that administrative or civil penalties were available, federal interest was minimal, and deterrent value was lacking.

In 1981 and 1984 the OIG conducted three additional investigations concerning one of the eight coauthors originally investigated from November 1980 to April 1981. In the original investigation, the allegation that this physician had improperly accepted remuneration from a drug company was not sustained. The three subsequent investigations

[8]VA physicians may not engage in outside professional activities for remuneration except under restricted circumstances and with VA authorization. VA full-time physicians are required to report outside income annually.

addressed allegations of his involvement in a private clinic and acceptance of honoraria from drug companies for lectures allegedly made during VA duty hours.

The OIG advised us that the second investigation in 1981 was initiated because of an allegation that the physician was a partner in a private clinic, which violated VA regulations. This allegation was sustained, but there was no evidence to indicate that the physician benefited financially from this association or that he served as a physician with the private clinic. VA gave him a formal letter of admonishment citing his participation in an activity that gave the appearance of being a conflict of interest. The physician resigned his position with the private clinic.

The two other investigations of this physician in 1984 involved allegations that four drug companies paid him for six lectures delivered during VA duty hours. These investigations revealed that he was paid $9,341 in honoraria and expenses by one company but disclosed no payments by the other companies. The allegations of lectures during duty hours were not sustained.

The OIG determined that the physician had not obtained prior approval from the Long Beach Medical Center Director for any of the six lectures, as required by VA regulations. Also, he violated regulations by not reporting on his annual "Report of Remuneration for Outside Professional Activities" that he had received the honoraria. VA issued him a formal letter of admonishment for this violation. VA referred these matters to the Department of Justice in August 1985, but Justice declined to prosecute.

Other VA Investigations of Research Activities at Long Beach Medical Center

Collectively, the OIG and the Chief Medical Inspector have investigated five Long Beach researchers since 1973, in addition to the eight coauthors of Dr. Aronow. The investigations were of allegations that they accepted unauthorized remuneration from drug companies in violation of VA guidelines or conducted unauthorized research studies. Allegations against two were sustained. The details follow:

Unauthorized remuneration. At the same time (1980 to 1981) that Dr. Aronow and his coauthors were investigated for alleged improper remuneration from drug companies, the OIG also investigated two other Long Beach researchers. One had allegedly failed to report receiving

$14,000 from a drug company; the other had allegedly received payments, the amount of which was not included in the report. The allegations concerning these two researchers were not sustained.

Unauthorized research. Since 1973, the OIG had investigated two other Long Beach Medical Center physicians for allegedly conducting unauthorized research studies. A 1976 investigation disclosed that the full-time physician, without VA approval, conducted a 6-month research project regarding the effects of diet and exercise on patients with severe peripheral vascular disease. The study was for a private foundation from which the physician received remuneration. The investigators found that by not obtaining appropriate authorization from the center's R&D committee, the physician had improperly used VA facilities, equipment, and personnel. The physician resigned from VA before his actions were discovered. VA referred the matter to the Department of Justice for criminal prosecution, but Justice declined the case.

A 1978 investigation involved a VA physician whom FDA investigated for possible irregularities in his research on the efficacy of various drugs to treat Parkinson's disease. The investigation determined that he engaged in unauthorized research and failed to deposit money received into the General Post Fund, submitted a false travel voucher in connection with his research, and may have submitted false documents regarding his educational background to the Ohio Medical Board. The physician resigned from VA before the investigation was completed.

Funds he improperly received from the drug companies and the false travel voucher were recovered. VA gave the Ohio Medical Board information about his submission of false educational background documents. As a result of the FDA investigation, he pleaded guilty in a federal district court to submitting false records to FDA in connection with his research studies. He was fined $5,000, placed on 5 years' probation, and ordered not to practice medicine unless lawfully licensed or to take part in any medical research investigations.

Unauthorized research and funding. In 1982, VA's Medical Inspector investigated one other Long Beach Medical Center researcher who allegedly conducted research for a drug company without the knowledge or approval of VA officials and sought research funding from the company without VA authorization. These allegations were not sustained, and the physician was found to have complied with pertinent VA research guidelines.

Conclusions

VA's actions after finding that Dr. Aronow did not obtain informed consent from VA patients participating in his research studies involving cardiac catheterization were appropriate and effective.

We could not determine whether VA should have taken other actions against Dr. Aronow in regard to questions raised about his other research practices because detailed documentation was not available.

The OIG's investigation of allegations concerning receipt of unauthorized payments from drug companies by VA medical research investigators at the Long Beach Medical Center, including Dr. Aronow's coauthors since 1973, were timely. Also, where allegations were sustained, VA acted responsibly, taking corrective actions by issuing pertinent guidance and admonishing, through established administrative and legal procedures, those not complying with VA guidelines.

Objectives, Scope, and Methodology

The objectives of our review were to provide information and to make determinations concerning five aspects of drug company-funded medical research in VA medical facilities, as requested by the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce (see p. 1). Our work was carried out from November 1984 to January 1986.

At VA headquarters' Department of Medicine and Surgery, Office of the ACMD/R&D, Office of the ACMD/Professional Services, Medical Inspector and Evaluation Office, and OIG in Washington, D.C., we interviewed responsible officials and obtained pertinent documentation.

We visited the VA Medical Center in Long Beach, California; the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin; and the VA Medical Center in East Orange, New Jersey. Through these visits, we intended to learn how VA investigators carry out research studies for drug companies and to evaluate VA's financial and nonfinancial controls over drug company research funds. The Chairman specifically requested that the Long Beach medical facility be included in our review. We selected the other two medical centers because, during fiscal year 1984, each

- received drug company funds for medical research through outside institutions and through direct donations for the VA General Post Fund,
- received relatively large amounts of such funds,
- had a relatively large number of active research studies, and
- reported that at least five investigators worked on 10 or more drug company-funded research studies.

We met with officials from three drug companies, selected from those that sponsored research projects at these three VA medical facilities. Our purpose was to obtain information on their funding arrangements with VA investigators, the objectives of the studies, and their understanding of VA guidelines regarding research funding. The companies visited were:

- E.R. Squibb & Sons, Inc., Princeton, New Jersey.
- Hoffmann-LaRoche, Inc., Nutley, New Jersey.
- Pfizer, Inc., New York City.

Collectively these three companies sponsored research studies at 51 VA medical centers during fiscal year 1984.

To determine whether VA's practice of directly receiving drug company donations to conduct medical research violated any federal laws or regulations, we reviewed applicable statutes and regulations and pertinent case law. Also, we met with an assistant general counsel from VA's Office of General Counsel to discuss the legal implications of donations made by drug companies to the General Post Fund.

To learn the extent to which VA investigators carry out studies for drug firms, we used nationwide fiscal year 1984 data extracted from VA's RDIS file. These were the most current data available at the time of our review. RDIS contains data on VA research studies as reported by VA investigators, including each study's source(s) and amounts of funding. We did not assess the reliability or accuracy of RDIS data, because this would have required significant additional audit effort.

To determine the extent to which drug companies provide research funds to VA, we reviewed available VA research and financial records, including the accounts of the General Post Fund for fiscal years 1983 and 1984, the most current data available. At the time of our review, the OIG was auditing drug company funds placed in the accounts of affiliated medical schools and other outside institutions. Because of this and to avoid duplication of effort, we did not obtain information about the use of those funds or determine whether cost reimbursement to VA from the funds involved an inappropriate supplement to VA's appropriation. We did, however, obtain data from the three VA medical centers visited to determine when and why drug company research funds were placed in affiliated medical school accounts rather than the General Post Fund.

To learn whether drug companies provide sufficient funds to cover VA's costs related to the research, we reviewed VA regulations, guidelines, and procedures and pertinent research and financial documents. We also discussed this issue with responsible central office officials, top officials in the three medical centers we visited, and representatives from the three drug companies we visited.

We conducted a computer literature search of the MEDLINE data base to identify the publications of Dr. Wilbert S. Aronow and his coauthors since 1973 and also contacted the VA OIG. Using MEDLINE, which is produced by the U.S. National Library of Medicine, with citations from over 3,000 international journals, we identified 149 of Dr. Aronow's coauthors. At our request, the OIG examined its files to determine which of the 149 individuals were present or former VA employees and whether

any of them had been investigated by the OIG between 1973 and April 1985.

To determine if there were other VA investigations of research activities at the Long Beach Medical Center from 1973 to April 1985, we contacted VA headquarters officials at the Office of the ACMD/R&D, the ACMD/Professional Services, the Office of the Chief Medical Inspector, and the OIG.

We discussed our findings with responsible officials in VA's central office and the three medical centers we visited. As requested by the Chairman's office, however, we did not obtain the views of responsible VA officials on our conclusions and recommendations or request official VA comments on a draft of this report.

Except as noted above, our review was conducted in accordance with generally accepted government auditing standards.

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